Filing Date: February 27, 2004

Title: METHOD AND APPARATUS FOR DEVICE CONTROLLED GENE EXPRESSION

### **REMARKS**

This responds to the Office Action dated on June 11, 2008.

Claim 1 is amended; and claim 152 is added; as a result, claims 1-7, 10-38, 41-148, and 150-152 are now pending in this application.

# The Non-Statutory Obviousness-Type Double Patenting Rejections

Claims 1-3, 10-13 and 150-151 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36, 38-78 and 96-111 of copending U.S. application Serial No. 10/890,825 in view of Padua (U.S. published application No. 2003/0204206). Claims 1-3, 10-13 and 150-151 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 of copending U.S. application Serial No. 11/220,397. Claims 1-3, 10-13 and 150-151 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-41 of copending U.S. application Serial No. 11/276,077.

Applicant notes that U.S. application Serial Nos. 10/890,825, 11/220,397 and 11/276,077 have not yet issued and are pending. Therefore, a terminal disclaimer is not required in these matters until issuance of one of them. If a terminal disclaimer is required in any of Serial Nos. 10/890,825, 11/220,397 and 11/276,077, it can be requested by the Office before issuance of those matters.

### The 35 U.S.C. § 102 Rejections

Claims 1-2, 13 and 150-151 were rejected under 35 U.S.C. § 102(a) and § 102(e) as being anticipated by Padua et al. (U.S. Publication No. 2003/0204206, hereinafter "Padua").

#### Claim 1

Applicant respectfully traverses the rejection and submits that the Office Action does not set forth a proper prima facie case of anticipation because the cited portions of Padua do not provide the claimed subject matter. For example, Applicant is unable to find in the cited portions of Padua, among other things, a controller adapted to produce a gene regulatory control signal,

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transmit the gene regulatory signal to a gene regulatory signal delivery device to trigger an emission of a regulatory signal in response to a detection of a predetermined cardiac condition, and quantitatively control the emission of the regulatory signal based on one or more condition parameters, as recited in claim 1.

The Office Action asserts, in paragraph 20, under Response to Arguments:

Although the parameters of Padua may be "predetermined", such predetermined parameters are used to quantitatively control and regulate the electric field regulatory signal for subsequently controlling and regulating the delivery of therapeutic gene products (emphasis added). The quantitative control is triggered, and is therefore, based on the event detector determined one or more condition parameters.

It is believed, however, with "predetermined parameters", the alleged controller of Padua does not quantitatively control the emission of the regulatory signal based on one or more condition parameters as recited in claim 1, and therefore differs from the controller recited in claim 1.

Applicant respectfully requests reconsideration and allowance of claim 1.

### Claims 2, 13 and 150-151

Applicant respectfully traverses the rejection. Claims 2 and 13 are dependent on claim 1, and claims 150-151 are dependent in part on claim 1, which is believed to be allowable for at least the reasons set forth above. Therefore, the discussion above for claim 1 is incorporated herein to support the patentability of claims 2, 13 and 150-151.

Applicant respectfully requests reconsideration and allowance of claims 2, 13 and 150-151.

# The 35 U.S.C. § 102/§103 Rejections

Claims 10-12 were rejected under 35 U.S.C. § 102(a) and § 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being obvious over Padua in view of Donahue et al. (U.S. Publication No. 2002/0155101, hereinafter "Donahue").

Applicant respectfully traverses the rejection. Claims 10-12 are dependent on claim 1. Claim 1 is believed to be allowable for at least the reasons set forth above. It is believed that the addition of Donahue does not remedy the deficiency of Padua as discussed above. Therefore, the discussion above for claim 1 is incorporated herein to support the patentability of claims 10-12.

Applicant respectfully requests reconsideration and allowance of claims 10-12.

Serial Number: 10/788,906

Filing Date: February 27, 2004

Title: METHOD AND APPARATUS FOR DEVICE CONTROLLED GENE EXPRESSION

# The 35 U.S.C. § 103 Rejection

Page 24

Dkt: 279.696US1

Claim 3 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Padua.

Applicant respectfully traverses the rejection. Claim 3 is dependent on claim 1, which is believed to be allowable for at least the reasons set forth above. Therefore, the discussion above for claim 1 is incorporated herein to support the patentability of claim 3.

Applicant respectfully requests reconsideration and allowance of claim 3.

# New Claim

New claim 152 has been added. Support for the new clams is found, for example, on page 24, lines 7-15 of the present application. Applicant believes that no new matter is added and that the new claims are appropriate for consideration in the present application.

Applicant respectfully requests consideration and allowance of claim 152.

# CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's representative at (612) 373-6959 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

> Respectfully submitted, SCHWEGMAN, LUNDBERG & WOESSNER, P.A. P.O. Box 2938 Minneapolis, MN 55402 (612) 373-6959

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box

1450, Alexandria, VA 22313-1450 on this \_\_\_\_\_/\_ day of September, 2008.

Signature

Name